F ENT COOPERATION TREA

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissioner for Patents
United States Patent and Trademark Office
Box PCT
Washington, D.C.20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 10 August 2000 (10.08.00)	
International application No. PCT/GB99/04070	**Applicant's or agent's file reference** PPR,006.pct
International filing date (day/month/year) 08 December 1999 (08.12.99)	**Priority date** (day/month/year) 08 December 1998 (08.12.98)
Applicant LEIGH, Steven et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

05 July 2000 (05.07.00)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer S. Mafla
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
PPR,006.pct		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB99/04070	08/12/1999	08/12/1998
International Patent Classification (IPC) or national classification and IPC A61K9/14		
Applicant PHARES PHARMACEUTICAL RESEARCH N.V. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 9 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☒ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
05/07/2000	22.03.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Heirbaut, M Telephone No. +49 89 2399 8642

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB99/04070

I. Basis f the r port

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).)*:
Description, pages:

1-31 as originally filed

Claims, No.:

1-23 as received on 26/02/2001 with letter of 23/02/2001

Drawings, sheets:

1/2,2/2 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☒ the claims, Nos.: 24-38

☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)
see separate sheet

6. Additional observations, if necessary:

II. Priority

1. ☐ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:

☐ copy of the earlier application whose priority has been claimed.

☐ translation of the earlier application whose priority has been claimed.

2. ☒ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid.

Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-38
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-38
Industrial applicability (IA)	Yes:	Claims	1-38
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

I

1 The amended set of claims do not meet the requirements of Art. 34(2)(b) PCT, as they introduce subject-matter which extends beyond the content of the application as originally filed. There is no support in the application as originally filed for the features:

a. "**a biologically effective amount** of at least one biologically active compound" in amended claim 1, as the application as originally filed only discloses "a biologically active compound" in this context (see in particular claim 1 as originally filed)

b. "**a bilayer forming** phospholipid" in amended claim 1, as the application as originally filed only discloses "a phospholipid" in this context (see in particular page 10, line 1 as originally filed)

c. "**a salt** of carboxymethylcellulose", "alginic acid or **a salt thereof**" and "a starch modified **with anionic groups**" in amended claim 2, as the application as originally filed only discloses "sodium carboxymethylcellulose", "sodium alginate" and "modified starch" in this context (see in particular table 2, page 16 of the application as originally filed)

This opinion has been established as if the above mentioned amendments had not been made and is therefore based on the application as originally filed (Rule 70.2 (c) PCT).

V

1 Reference is made to the following documents (D):

D1: WO-A-9 858 629
D2: EP-A-0 181 287
D3: EP-A-0 635 218

D4: DE-A-19 531 277

D5: DATABASE WPI Week 9440 Derwent Publications Ltd., London, GB; AN 1994-321236 XP002136412 & JP-A-06 245719

D6: DATABASE WPI Week 0296 Derwent Publications Ltd., London, GB; AN 1996-017127 XP002136413 & JP-A-07 291854

2 The subject-matter of present independent claim 1 (carrier composition) does not meet the requirements of novelty (Article 33(2) PCT) in the light of any of the prior art documents D1-D6, which teach the combination of features indicated in said claim.

Document D1, with the international filing date 19.06.1998 and international publication date 30.12.1998, claims the priority date of 20.06.1997 (GB 9713140.3), and the priority date of 08.12.1998 was not validly claimed by the present application, as the priority document does not disclose a carrier composition with at least one **single chain amphipathic lipid** and/or at least one **double chain amphipathic lipid**. Document D1 teaches a carrier composition for lipophilic materials with improved bioavailability, comprising a biologically effective amount of the biologically active lipophilic compound dissolved in or associated with at least one micelle-forming lipid (see in particular page 1, paragraph 1 of D1). Mixtures of diacyl and monoacyl lipids are preferred for solubilising CyA (see in particular page 8, lines 22-27 of D1). Solid compositions are described comprising CyA (ie biologically active compound), enzyme-modified lipid and a polymer as an excipient (ie PEG, Poloxamer, Polysorbate or Polyoxol) dissolved in ethanol, followed by ethanol evaporation (see in particular examples 11-14, 16-18, 23 and 25, pages 25-26 of D1).

Document D2 teaches **lyophilised dry** substances comprising 4-hydroxy- or 4-acycloxy-4-androsten-3,17-dione and a mixture of at least one phospholipid and at least one PEG (see in particular claim 1 of D2). A method of producing said dry substances, comprising suspending 4-hydroxy- or 4-acycloxy-4-androsten-3,17-dione and a mixture of at least one phospholipid and at least one PEG in an aqueous suspension and lyophilising the resulting suspension (see in particular claim 7 of D2). A composition is described comprising 4-hydroxy-4-androsten-

3,17-dione (ie biologically active compound), Epikuron 200 (ie a diacyl membrane lipid) and ascorbylpalmitate (ie a monoacyl membrane lipid) and Carbowax 4000 (ie a polymer) suspended in an aqueous thiomersal solution and lyophilised (see in particular example 2, page 7 of D2).

Document D3 teaches a composition comprising soybean lecithin (ie amphipathic lipid), milk whey and sodium caseinate (ie a polymeric material). The dispersion in water is freeze-dried, resulting in a **solid** product (see in particular example 5 of D3).

Document D4 teaches pharmaceutical compositions comprising hydroxypropyl-cellulose (ie a polymer), a pharmaceutically active compound and lecithin (ie a diacyl membrane lipid) **and/or** ricinus oil (ie a monoacyl membrane lipid) as an amphiphilic lipid (see in particular examples 1-9 of D4).

Document D5 teaches a composition comprising fatty acid esters (glycerin, sucrose etc.) (ie a monoacyl membrane lipid), lecithin (ie a diacyl membrane lipid), starch or its dehydrates (ie a polymer) and organic acid, glycerin, fatty acids (ie a biologically active material), prepared by spray drying (see abstract of D5).

Document D6 teaches a composition comprising a sparingly soluble drug, a hydrophilic polymer and solubilising agent in the presence of an aqueous solvent, and removing the solvent. The solubilising agent is preferably polyhydric alcohol, polyhydric alcohol ether or ester, lecithin (see abstract of D6).

3 The subject-matter of present independent claim 26 (method) does not meet the requirements of novelty (Article 33(2) PCT) in the light of any of the prior art documents D1-D3 or D5-D6, which teach the combination of features indicated in said claim (see paragraph 2 of this communication).

4 The subject-matter of present independent claim 31 (lipid composition) does not meet the requirements of novelty (Article 33(2) PCT) in the light of any of the prior art documents D1-D2 or D4-D5, which teach the combination of features indicated in said claim (see paragraph 2 of this communication).

The parameter "when stored in a glass container remains free flowing after storage for 3 months at 40°C and 75% relative humidity" does not distinguish the subject-matter of present claim 31 from the teaching of documents D1-D6, as the compositions disclosed in documents D1-D6 comprise the ingredients indicated in present claim 31 (PCT Guidelines C-IV, 7.5).

5 Concerning the question whether the subject-matter of the present independent claims meets the requirements of inventive step (Article 33(3) PCT), it is stressed that cited documents D1-D2, D4 and D6 are related to the same technical problem as is the present application, ie to provide carrier compositions for pharmaceutically active agents.

VII

1 The present application does not meet the requirements of Rule 5.1(a)(ii) PCT, as the relevant background art disclosed in the documents D2-D6 has not been mentioned in the description, nor have these documents been identified therein.

VIII

1 The present application does not meet the requirements of clarity (Article 6 PCT).

1.1 It is clear from the present description that the presence of at least 10% by weight of at least one polymer, based on the total weight of the solid composition, is required to substantially harden the soft lipid (see in particular page 16, lines 8-11). Hence, this feature is essential to the definition of the invention. Since present independent claims 1 and 31 do not indicate said feature, they do not meet the requirements of Article 6 PCT and Rule 6.3 (b) PCT that any independent claim must contain all the technical features essential to the definition of the invention.

1.2 The feature "a natural gum **or a derivative thereof**" in present claim 7 and the present description is vague.

1.3 The feature "based on the weight of said **base composition**" in present claim 12, is unclear, as the preceding claims to which said claim refers do not indicate a **base composition**.

1.4 The misspelled feature "bioflav**e**noid" in present claim 22 should be replaced by "bioflav**o**noid".

CLAIMS

1. A composition for delivering a biologically active compound comprising:

(a) a biologically effective amount of at least one biologically active compound;

(b) a mixture of lipids in which the biologically active compound is dissolved or dispersed, said mixture comprising as first component a single chain amphipathic lipid which is a monoacyl derivative of a phospholipid, glycolipid, sphingolipid or a polyethylene glycol derived monoacyl phospholipid and as second component at least one double chain amphipathic lipid which is a bilayer forming phospholipid; and

(c) a polymeric material associated with and hardening said lipid or lipids so that they become friable or crushable at ambient temperatures, and selected from natural gums and derivatives thereof, gelatine, partially hydrolysed gelatine, celluloses, starches, modified starches, charged pharmaceutical polymers and polyvinylpyrrolidone.

2. The composition of claim 1, wherein the polymeric material is a salt of carboxymethylcellulose, alginic acid or a salt thereof, a starch modified with anionic groups, agar, carrageenan, gum arabic, gum tragacanth, gum xanthan, pectin, carboxypolymethylene, a methyl vinyl ether/maleic acid copolymer, a methacrylic acid copolymer, an ammonio methacrylate copolymer, a basic polymethacrylate,or chitosan,

3. The composition of claim 1 or 2, comprising an enzyme digested lecithin.

4. The composition of claim 3, comprising 60-80 mol % of monoacyl lipid.

5. The composition of any preceding claim, wherein there is present at least 10 wt % of the polymer based on the weight of said base composition.

6. The composition of any preceding claim, further comprising a sugar.

7. The composition of any preceding claim, further comprising a polyol, sucrose ester or polyglyceryl ester of a higher fatty acid or another polyol ester of a higher fatty acid.

8. The composition of any preceding claim, wherein the ratio by weight of the lipid to the active compound is from 40:1 to 1:40.

9. The composition of any preceding claim, wherein the active compound is present in molecular dispersion in the lipid.

10. The composition of any of claims 1-8, wherein the active compound is present as discrete particles in the composition.

11. The composition of claim 10, wherein the size of said particles is not more than 1μm.

12. The composition of any preceding claim, wherein the biologically active compound is cyclosporin A, Taxol, tacrolimus or a rapamycin.

13. The composition of any of claims 1-11, wherein the biologically active compound is insulin, calcitonin or heparin.

14. The composition of any of claims 1-11, wherein the biologically active compound is ubiquinone, a tocopherol, a carotenoid or a bioflavenoid.

15. The composition of any preceding claim, which is of powder of size 50-2000 μm.

16. The composition of any preceding claim, which is of powder of size 50-1000 μm.

17. The composition of any of claims 1-14, which is of granules of size 1-5 mm.

18. A method for making the composition of any preceding claim, which comprises dissolving or dispersing the ingredients in a solvent and removing said solvent.

19. The method of claim 18, wherein the lipid and biologically active compound (if present) are dissolved in ethanol, the polymer is dissolved in water, the aqueous and ethanolic solutions are mixed, and the mixture is dried.

20. The method of claim 18 or 19, comprising the further step of comminuting the composition after the solvent has been removed.

21. The method of claim 20, comprising the further step of forming siad comminuted composition into a tablet.

22. The method of claim 20, comprising the further step of filling said comminuted composition into a capsule.

23. The composition of any of claims 1-19 which is a powder that when stored in a glass container remains free flowing after storage for 3 months at 40°C and 75% relative humidity.

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

COLE, Paul Gilbert
LUCAS & CO
135 Westhall Road
Warlingham
Surrey CR6 9HJ
GRANDE BRETAGNE

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing *(day/month/year)*	22.03.2001
Applicant's or agent's file reference	**IMPORTANT NOTIFICATION**
PPR,006.pct	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB99/04070	08/12/1999	08/12/1998

Applicant
PHARES PHARMACEUTICAL RESEARCH N.V. et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/	Authorized officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Longo, E Tel.+49 89 2399-8141

Form PCT/IPEA/416 (July 1992)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
PPR,006.pct		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB99/04070	08/12/1999	08/12/1998
International Patent Classification (IPC) or national classification and IPC A61K9/14		
Applicant PHARES PHARMACEUTICAL RESEARCH N.V. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 9 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☒ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
05/07/2000	22.03.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Heirbaut, M Telephone No. +49 89 2399 8642

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB99/04070

I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).)*:
Description, pages:

1-31	as originally filed				

Claims, No.:

1-23	as received on	26/02/2001	with letter of	23/02/2001

Drawings, sheets:

1/2,2/2	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   ☐ the language of publication of the international application (under Rule 48.3(b)).
   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.
   ☐ filed together with the international application in computer readable form.
   ☐ furnished subsequently to this Authority in written form.
   ☐ furnished subsequently to this Authority in computer readable form.
   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:
   ☒ the claims, Nos.: 24-38

☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)
   see separate sheet

6. Additional observations, if necessary:

II. Priority

1. ☐ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:

   ☐ copy of the earlier application whose priority has been claimed.

   ☐ translation of the earlier application whose priority has been claimed.

2. ☒ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid.

   Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

V. R asoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-38
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-38
Industrial applicability (IA)	Yes:	Claims	1-38
	No:	Claims	

2. Citations and explanations
   see separate sheet

VII. C rtain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION** see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
PPR,006.pct		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/GB 99/04070	08/12/1999	08/12/1998
Applicant		
PHARES PHARMACEUTICAL RESEARCH N.V. et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [ ] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. _____

   [ ] as suggested by the applicant.

   [ ] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

   [X] None of the figures.

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

WIPO OMPI

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 :
A61K 9/14, 47/24

A1

(11) International Publication Number: WO 00/33817

(43) International Publication Date: 15 June 2000 (15.06.00)

(21) International Application Number: PCT/GB99/04070

(22) International Filing Date: 8 December 1999 (08.12.99)

(30) Priority Data:

9827006.9	8 December 1998 (08.12.98)	GB
9925365.0	27 October 1999 (27.10.99)	GB

(71) Applicant *(for all designated States except US)*: PHARES PHARMACEUTICAL RESEARCH N.V. [NL/NL]; 14 John B Gorsiraweg, P.O. Box 3889, Curacao (AN).

(72) Inventors; and

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(54) Title: PHOSPHOLIPID COMPOSITIONS

(57) Abstract

The present invention relates to the preparation of powder or solid compositions comprising single and double chain amphiphilic lipids in association with polymers which harden them so that they can be comminuted into powder or granules. The compositions can act as carriers for biologically active compounds and can be administered to living organisms. Such a composition may comprise a biologically active compound and monoacyl and diacyl membrane lipid in association with a polymer, said composition being a solid that when stored in a glass container remains free flowing after 3 months at 40 °C and 75 % relative humidity. The lipids may be selected from those which have GRAS status e.g. enzyme modified lecithin, and the polymer may be selected from natural polysaccharide polymers, starches and their derivatives, cellulose and its derivatives and gelatines.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
GB 99/04070

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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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[X] Further documents are listed in the continuation of box C.

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Date of the actual completion of the international search	Date of mailing of the international search report
26 April 2000	09/05/2000

Name and mailing address of the ISA	Authorized officer
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